ANTI-DIARRHEAL- loperamide hydrochloride capsule, liquid filled QUALITY CHOICE (Chain Drug Marketing Association)

Drug Facts

Active ingredient (in each capsule)

Loperamide HCl 2 mg

Purpose

Anti-diarrheal

Use

controls symptoms of diarrhea, including Travelers' Diarrhea

Warnings

Allergy alert: Do not use if you have ever had a rash or other allergic reaction to loperamide HCl.

Heart alert: Taking more than directed can cause serious heart problems or death.

Do not use

- if you have bloody or black stool
- in children under 12 years of age

Ask a doctor before use if you have

- fever
- mucus in the stool
- a history of liver disease

Ask a doctor or pharmacist before use if you are

taking antibiotics.

When using this product

tiredness, drowsiness, or dizziness may occur. Be careful when driving or operating machinery.

Stop use and ask a doctor if

- symptoms get worse
- diarrhea lasts for more than 2 days
- you get abdominal swelling or bulging. These may be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- drink plenty of clear fluids to help prevent dehydration caused by diarrhea
- not for use in children under 12 years of age
- adults and children 12 years of age and over: 2 softgels after the first loose stool; 1 softgel after each subsequent loose stool; but no more than 4 softgels in 24 hours

Other information

- store at 20°-25°C (68°-77°F) Protect from light.
- avoid excessive heat above 40°C (104°F)
- do not use if carton or blister unit is open or torn
- see side panel for lot number and expiration date

Inactive ingredients

butylated hydroxyanisole, edible ink, FD&C blue #1, gelatin, glycerin, glyceryl caprylate, polyoxyl 40 hydrogenated castor oil, purified water

Questions or comments?

Call 1-248-449-9300 Monday-Friday 9AM-5PM EST

Principal Display Panel

†Compare to the active ingredient in Imodium® A-D

Anti-Diarrheal

Controls The Symptoms Of Diarrhea

Loperamide HCl, 2 mg

Suitable For Adults And Children 12 Years And Over

*Each Liquid-Filled Capsule Contains 2 mg Loperamide HCl

Softgels*

Distributed by C.D.M.A., Inc.®

43157 W. Nine Mile

Novi, MI 48376-0995

www.qualitychoice.com

Questions: 248-449-9300

THIS PRODUCT IS PACKAGED IN A CHILD-RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

†This product is not manufactured or distributed by McNeil Consumer & Specialty Pharmaceuticals, distributor of Imodium® A-D.

Product Label

signs of a serious condition.

- you get abdominal swelling or bulging. These may be
 - diarrhea lasts for more than 2 days
 - symptoms get worse

Stop use and ask a doctor if

When using this product tiredness, drowsiness, or dizziness may occur. Be careful when driving or operating machinery.

sutipiotics.

Ask a doctor or pharmacist before use if you are taking

- Ask a doctor before use if you have

 fever muucus in the stool m a history of liver disease
 - in children under 12 years of age
 - if you have bloody or black stool

Do not use

heart problems or death.

other allergic reaction to loperamide HCI.

Heart alert: Taking more than directed can cause serious

Allergy alert: Do not use if you have ever had a rash or

Warnings

Travelers' Diarrhea.

USE Controls symptoms of diamhea, including

(in each čapsule)

Active ingredient

Drug Facts

Questions or comments?

1916

Inactive ingredients butylated hydroxyanisole, edible ink, FD&C blue #1, gelatin, glycerin, glyceryl caprylate, polyoxyl 40 hydrogenated castor oil, purified

- see side panel for lot number and expiration date
- do not use if carton or blister unit is open or torn
 - avoid excessive heat above 40°C (104°F)
- store at 20°-25°C (68°-77°F). Protect from light.

Other information

4 softgels in 24 hours

- softgels after the first loose stool; 1 softgel after each subsequent loose stool; but no more than
- not for use in children under 12 years of age ■ adults and children 12 years of age and over: 2
 - drink plenty of clear fluids to help prevent
 dehydration caused by diarrhea

Directions

Purpose

before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

If pregnant or breast-feeding, ask a health professional

Drug Facts (continued)

QC QUALITY CHOICE

Anti-Diarrheal

Controls Symptoms Of Diarrhea

NDC 63868-748-12

†Compare to the active ingredient in Imodium® A-D



Anti-Diarrheal

Controls Symptoms Of Diarrhea

Loperamide HCI, 2 mg

Suitable For Adults And Children 12 Years And Over

*Each Liquid-Filled Capsule Contains 2 mg Loperamide HCI



Lot No.: Exp. Date:

THIS PRODUCT IS PACKAGED IN A CHILD-RESISTANT AN

12 Softgels*



REV # 9/16 PLD-E45J FC003593



QUALITY CHOICE Anti-Diarrheal

ANTI-DIARRHEAL

loperamide hydrochloride capsule, liquid filled

Product	Inform	ation
Product		auon

Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4II)	LOPERAMIDE HYDROCHLORIDE	2 mg	

Inactive Ingredients		
Ingredient Name	Strength	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
GELATIN (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6A3C0OX)		
GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)		
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)		
WATER (UNII: 059QF0KO0R)		

Product Characteristics			
Color	blue	Score	no score
Shape	CAPSULE	Size	10mm
Flavor		Imprint Code	P13
Contains			

ı	Packaging			
4	# Item Code	Package Description	Marketing Start Date	Marketing End Date
]	NDC:63868- 748-12	1 in 1 CARTON	05/31/2013	12/29/2023
]	L	12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing I	Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA021855	05/31/2013	12/29/2023	

Labeler - QUALITY CHOICE (Chain Drug Marketing Association) (011920774)

Revised: 11/2021 QUALITY CHOICE (Chain Drug Marketing Association)